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MAY 21 2010

510(k) Summary

Date Summary Prepared:	April 21, 2010
Applicant:	Medtronic Neuromodulation 7000 Central Ave., N.E. Minneapolis, MN 55432
Contact:	Thomas Reichel Regulatory Affairs Specialist 763-526-9693 763-526-6246 (fax)

Trade Name: Prostiva RF Therapy Model 8929 Hand Piece

Classification Name: 21 CFR 876.4300 (Endoscopic electrosurgical unit and accessories)

Name of Predicate Device: Prostiva RF Therapy Model 8929 Hand Piece

Device Description

Medtronic Prostiva RF Therapy is a minimally invasive treatment for patients with lower urinary tract symptoms due to benign prostatic hyperplasia (BPH). Prostiva® RF Therapy System uses precisely focused radio frequency (RF) energy to ablate prostate tissue. The Prostiva RF Therapy Model 8929 Hand Piece is the delivery system component of the Prostiva RF Therapy System.

Indications for Use

The Prostiva RF Therapy System is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostate sizes between 20 and 50 cm^3.

Performance Standards

No applicable mandatory performance standards or special controls exist for this device.

Substantial Equivalence

The conclusions from assessing the material change and results from biocompatibility testing confirm that the change to the insulation of the thermocouple wires contained in the urethra tube does not affect the functionality or biocompatibility of the device and that the device is therefore substantially equivalent to the currently marketed device. There are no changes in device specifications or indications for use.

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Summary of Testing

A material change assessment was conducted and biocompatibility testing was performed to support the material change in the Prostiva RF Therapy Model 8929 Hand Piece device.

Conclusion

The modified device is substantially equivalent to the currently marketed PROSTIVA RF Therapy Model 8929 Hand Piece based upon the conclusion of the material change assessment and biocompatibility test results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Thomas J. Reichel
Regulatory Affairs Specialist
Medtronic Neuromodulation
7000 Central Avenue, N.E., MS RCW235
MINNEAPOLIS MN 55432

MAY 21 2010

Re: K101139
Trade/Device Name: Prostiva® RF Therapy Model 8929 Hand Piece
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: KNS and GEI
Dated: April 21, 2010
Received: April 22, 2010

Dear Mr. Reichel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications Statement Form

510(k) Number (if known): [redacted] K101139

Device Name: Prostiva® RF Therapy Model 8929 Hand Piece

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X___ OR Over-The-Counter Use _____

Per 21 CFR 801.109

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K101139